

U.S. Serial No. 08/507,863  
Page 2

Interview

The undersigned wishes to thank Examiner Niland for the courtesies extended during the personal interview held for this application on March 17, 1997. Applicants arguments presented in this interview are accurately reflected in the Examiner Interview Summary Record and are further elaborated upon in the discussion below.

In this interview, Applicants maintained that the claimed subject matter of this application possessed surprising and unexpected results compared to the prior art which results rebutted the *prima facie* case of obviousness raised by the references relied upon in the rejection of Claims 1-15 maintained under 35 U.S.C. §103. Specifically, Applicants maintained that the compositions of this invention comprising a water insoluble contrast agent selected from tantalum, tantalum oxide and barium sulfate provided for a coherent solid material upon contact with an aqueous solution whereas similar compositions comprising a water soluble contrast agent (metrizamide) did not. Applicants further maintained that the viscosity data of Example 4 evidenced that the compositions of this invention were compatible since the addition of either barium sulfate or tantalum to a solution comprising an ethylene vinyl alcohol copolymer and dimethylsulfoxide (DMSO) did not materially alter the viscosity of the composition whereas the addition of metrizamide did. It was submitted that such data demonstrated a lack of interaction between the water insoluble contrast agent and the ethylene vinyl alcohol copolymer.

Based upon the above, Applicants submitted that these results were unexpected and surprising and, accordingly, rebutted any *prima facie* case of obviousness raised by the cited art.

Examiner Niland, while agreeing with the general premise of these arguments, suggested that data showing the formation of a coherent solid precipitate with injection of a composition comprising an ethylene vinyl alcohol copolymer having a vinyl alcohol content at least as great as Tanabe was required to render the data probative against the closest prior art.

U.S. Serial No. 08/507,863  
Page 3

The Examiner also requested confirmation of the characterization made by Dr. Greff during the interview that the precipitate formed by injection into saline of the metrizamide composition found in Example 3 of this application had the consistency of tissue/toilet paper when exposed to water which, within seconds after forming, began to disintegrate/fragment in the aqueous solution.

Based upon the above, it was agreed that the following composition would be tested in the manner of Example 3 to determine the quality of the precipitate formed:

- A. 8 weight percent ethylene vinyl alcohol copolymer having a vinyl alcohol content at least as great as that of Tanabe, U.S. Patent No. 5,443,454,
- B. 40 weight percent tantalum, and
- C. 52 weight percent DMSO.

Upon a review of Tanabe, the highest vinyl alcohol content in the ethylene vinyl alcohol copolymer recited in this patent is believed to be found at Col. 12, lines 22-29, wherein the vinyl alcohol content is 67 mole %.

In view of the above, the enclosed declaration of Richard Greff, Ph.D. is believed to provide the data requested by Examiner Niland. Specifically, this data employs a composition as described above containing an ethylene vinyl alcohol copolymer having 68 mole percent vinyl alcohol which is greater than the vinyl alcohol content of Tanabe as found at Col. 12, lines 22-29. This declaration then evaluates the precipitate formed by this composition and concludes, based on the data set forth therein, that the composition comprising 8 weight percent ethylene vinyl alcohol copolymer (68 mole percent vinyl alcohol, 32 mole percent ethylene), 52 weight percent of dimethyl sulfoxide (DMSO) and 40 weight percent tantalum formed a well defined solid mass or precipitate upon injection into saline.

The enclosed declaration of Richard Greff, Ph.D. also states that he has reviewed his data relative to the precipitate formed by injection into saline of the metrizamide composition found in Example 3 of this application and confirms that this precipitate has

U.S. Serial No. 08/507,863  
Page 4

the consistency of tissuc/toilet paper when exposed to water which, within seconds after forming, began to disintegrate/fragment.

Applicants submit that this declaration meets all of the requirements made by the USPTO during the interview.

Showing Under 37 C.F.R. §1.116(b)

As noted above, this response is being submitted pursuant to 37 C.F.R. §1.116(b) and, as required by §1.116(b), Applicants note the following:

(1) this response is necessary in order to present evidence to the Examiner as to unexpected and surprising results which would rebut any *prima facie* case of obviousness raised by the cited art; and

(2) this amendment was not presented prior to appeal in this application because consideration of filing such a declaration by Applicants was only made during the interview for this application conducted on March 17, 1997 which was after filing of the notice of appeal.

Accordingly, having complied with 37 C.F.R. §1.116(b), Applicants submit that consideration of this amendment is proper and that, in view of this amendment, this application is now in condition for allowance. A notice to that effect is earnestly solicited.

Respectfully submitted,  
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